



## REMARKS SECTION

### STATUS OF THE CLAIMS

Claims 2,4,6,8 and 11 are pending in the application.

Claims 2,4 and 11 were rejected under 35 USC§102(b) as being anticipated by Hoffman et al. '977 and De Goicoechea et al. '927.

Claims 2,4,6,8 and 11 were rejected under 35 USC§103(a) as being unpatentable over Quaid '744 in view of Goldstein et al. '037.

Claims 2,4,6,8 and 11 were rejected under 35USC§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 (Amended) is further amended by this Amendment B.

Following entry of this Amendment B, Claims 2 (Twice Amended), 4,6,8 and 11 remain pending in the application.

### REMARKS

#### SUMMARY OF THE INVENTION



A hybrid medical implant having a biocompatible, nonabsorbable core portion and a textured outer surface portion overlying the core portion wherein a portion of the outer surface portion is bioabsorbable. The hybrid implant is useful as a prosthesis for tissue augmentation and/or reconstruction. The core portion of the implant includes a body formed from a nonabsorbable, biocompatible implantable material such as silicone or urethane elastomer. The core portion may be either a solid body, a viscous gel body or a fluid-filled shell. The textured outer surface portion envelops the core portion and presents an irregular, textured surface to the exterior environment. The irregularities in the outer

surface are due to a plurality of bioabsorbable particles embedded in a nonbioabsorbable elastomer comprising the outermost surface of the implant and projecting outwardly from the outermost surface of the nonbioabsorbable elastomer. Since the bioabsorbable particles are embedded in the (nonbioabsorbable) core, after disintegration of the bioabsorbable particles due to bioabsorption thereof by the hosts body, the character and topography of the outer surface changes, leaving a plurality of craters in the outer surface where the particles were embedded. The irregular topography of the outer surface of the hybrid implant in accordance with the present invention changes following implantation.

#### The Rejection Under 35USC§102

Claims 2,4 and 11 were rejected under 35 USC§102(b) as being anticipated by Hoffman Jr. et al. Briefly, Hoffman, Jr. et al. '977 disclose an implantable synthetic vascular graft. The graft (prosthesis) comprises a porous tubular graft material such as a Dacron tube impregnated with a film comprising collagen. The collagen may or may not have a drug blended therewith. In any event, the collagen is not applied to the outer surface of the porous tube in the form of particles, nor do bioabsorbable particles (collagen) provide an outer surface having an irregular topography. The "irregular" topography in '977 is provided by molding the porous tube to be corrugated – a regular topography.

In contrast, the present invention discloses and claims a medical implant comprising a fluid-filled, nonbioabsorbable core enveloped by an outer shell that comprises a flexible nonbioabsorbable, nonporous elastomer, such as silicone elastomer, wherein the nonbioabsorbable elastomer has a plurality of bioabsorbable particles embedded therein and projecting outwardly from the outer surface of the outer shell and presenting an irregular topography. Support for the presently claimed subject matter is



provided in the specification on page 13, lines 3-16. The method disclosed for adhering bioabsorbable particulates to an outer shell having an uncured silicone outer surface provides a medical implant having the structural features recited in Claim 2 (Twice Amended).

De Goicoechea et al. discloses a vascular graft similar to the Hoffman, Jr. et al. graft wherein the collagen is applied to a porous tube as a film and massaged into the interstices of the tube. It is noted that in the present invention, the plurality of bioabsorbable particles are applied to the uncured surface of a nonporous core. In the prior art relied on by the examiner, the structure (i.e., topography) of the outer surface of the implants is determined by the topography of the outer surface of the core to which the collagen film is applied. In the present invention, the topography of the outer surface of the core is smooth and the irregular topography of the outer surface of the implant is due solely to the presence of discrete bioabsorbable particles embedded in the smooth surface of the core; a portion of the embedded particles projecting outwardly from the smooth surface of the core.

In order for a patent to qualify as a reference supporting a §102 (b) rejection, it must disclose each and every limitation of the rejected claim. It is settled that even only slight differences between the compared inventions prevent a rejection based on lack of novelty under §102. Anticipation under 35 USC§102 requires that the cited references demonstrate each and every element of the claimed invention. In view of the differences between the elements of the present invention and those of the prior art presented herein, it is requested that this rejection be withdrawn.

The Rejection Under 35USC§103

Claims 2,4,6,8 and 11 were rejected under 35USC§103(a) as being unpatentable over Quaid '744 IVO Goldstein et al. '037. The Examiner argues that Quaid teaches the present invention except that the bioabsorbable particles (salt crystals) do not contain an antibiotic. Applicant respectfully disagrees with the Examiner. Quaid teaches an implant wherein the surface is textured to permit tissue ingrowth and reduce capsular contracture following implantation within a body. In Quaid '744, salt particles are embedded into the uncured outermost layer of silicone elastomer on a shell. The elastomer is then cured and the salt particles are removed by dissolution in a suitable solvent prior to implantation within the body. Accordingly, the topography of the outer surface of a Quaid-type implant does not change following implantation within the body. Thus, even if antibiotics or other pharmaceutical agents in accordance with Goldstein et al. '037 were incorporated in the bioabsorbable particles of Quaid (i.e., salt crystals), since the crystals of Quaid are removed from the implant prior to implantation within a body, the combination of Goldstein et al. with Quaid would fail to provide the present invention.

The presently claimed invention discloses an outer shell wherein a portion of the shell is nonbioabsorbable and has a plurality of discrete, bioabsorbable particles embedded therein and projecting outwardly therefrom. In considering the question of obviousness of the claimed invention in view of the prior art relied upon, the applicant submits that the test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. The law requires an applicant to show only that the claimed combination of structure is non-obvious in view of the prior art under Deere. In fact, the CAFC has made it clear that an invention need not operate differently than the prior art to be patentable, but need only be structurally different.

In summary, under Deere (op.cit), and as set forth in MPEP §706.02, to establish a *prima facie* case of obviousness of a particular claim, the Patent Office must :

- (a) set forth differences in the claim over the applied references;
- (b) set forth the proposed modification of the references which would be necessary to arrive at the claimed subject matter; and
- (c) explain why the proposed modification would be obvious.

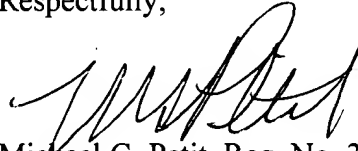
To satisfy step (c), the Patent Office must identify where the prior art provides a motivating suggestion to make the modifications proposed in step (b). In the present instance the combination of elements; specifically, a medical implant having a nonbioabsorbable core and a hybrid outer shell enveloping the core, wherein the hybrid outer shell comprises a nonbioabsorbable elastomer having a plurality of bioabsorbable particles embedded therein, and projecting outwardly therefrom, as recited in independent claim 2, are different from the elements in the prior art and, moreover, are not suggested by the prior art. In view of these clarifications regarding the difference between the elements of the present invention and the prior art it is requested that this rejection be withdrawn.

#### The Rejection Under 35USC§112

The claims of the application have been carefully reviewed in light of the objections raised by the Examiner in the outstanding Office Action. Specifically, independent Claim 2 has been further amended to more particularly point out and distinctly claim features that applicant regards as the invention. Antecedent basis for all terms recited is provided in the (Twice Amended) Claim 2. Applicant respectfully submits that the amended claims overcome the rejections under 35USC§112, and an indication to this effect is respectfully requested.

Entry of this amendment, reconsideration, favorable action and early allowance and publication of this application are respectfully requested. If there are any minor matters remaining, it is respectfully requested that the examiner contact the undersigned by phone so that possible minor changes may be discussed in order to expedite the prosecution of this case.

Respectfully,



Michael G. Petit, Reg. No. 30,795  
P. O. Box 91921  
Santa Barbara, CA 93190-1929  
Tel: 805-563-6556/Fax: 805-563-6615

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Michael G. Petit